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TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.

11/7/03

40/Letter
re IDS

To: Examiner Susan Tran
Re: U.S. Patent Application Serial No.: 09/403,429
Fax: 703-746-3139
No. Pgs.: 4
Our Ref. No. 2535 USOP (31)

Dear Examiner:

Thank you for your call of 11/6, indicating that the pending claims would be allowable if certain modifications were made, and a terminal disclaimer was filed.

I have received approval for the modification of the independent claims to include the amount of the sugar component as 5 to 97% by weight in accordance with the teaching of the specification at the bottom of page 9. Approval has been granted for the modification of claims 20, 30 and 32. Addition of the sugar in the amount indicated above to claim 21 is also approved.

Please also find enclosed a copy of PTO Form 1449 for the IDS filed 10/20/99 which has not yet been considered by the Examiner. A copy of the Notice of Acceptance, indicating receipt of that IDS by the PTO is also enclosed.

However, Applicants do not agree to the filing of a terminal disclaimer over U.S. Patent No. 6,586,004. Applicants do not believe that the pending claims represent identical subject matter to the

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claims of the '004 patent, so they do not see the basis for a statutory double patenting rejection.

Moreover, Applicants believe that the pending claims are patentably distinct from the claims of the '004 patent, so there is no basis for a non-statutory double-patenting rejection.

The Examiner is respectfully requested to consider the comparisons of Tables 1 and 2 of the specification, wherein formulations including L-HPC having 5.8% hydroxypropoxyl group content (LH-33) are compared to formulations including L-HPC having 5.8% hydroxypropoxyl group content (LH-32) are listed. The evaluations show the patentable distinction between the two formulations, a non-obvious result.

Therefore, Applicants respectfully request reconsideration of any double patenting rejection, and consideration of their previously filed IDS.

Applicants authorize the Examiner to add the weight limitation range for the sugar as discussed above, by Examiner's amendment.

Sincerely,

Elaine M Ramesh

Elaine M. Ramesh



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

U.S. APPLICATION NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/403429		2535USOP
INTERNATIONAL APPLICATION NO.		
PCT/JP99/04015		
LA. FILING DATE	PRIORITY DATE	
27 JUL 99	28 JUL 98	

PHILIPPE Y RIESEN
TAKEDA CHEMICAL INDUSTRIES
17 85 JUSOHONMACHI 2 CHOME
INTELLECTUAL PROPERTY DEPARTMENT
YODOGAWA KU OSAKA, JPX 53286 86

DATE MAILED: 04 APR 2000

NOTIFICATION OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C. 371
AND 37 CFR 1.494 OR 1.495

1. The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as ☒ a Designated Office (37 CFR 1.494), ☐ an Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is **ACCEPTED** for national patentability examination in the United States Patent and Trademark Office.

2. The United States Application Number assigned to the application is shown above and the relevant dates are:

20 OCT 99
35 U.S.C. 102(e) DATE

20 OCT 99
DATE OF RECEIPT OF
35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE "FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371(C) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

3. ☒ A request for immediate examination under 35 U.S.C. 371(f) was received on 20 OCT 99 and the application will be examined in turn.

4. The following items have been received:

- ☒ U.S. Basic National Fee.
☒ Copy of the international application in:
☐ a non-English language.
☒ English.
☐ Translation of the international application into English.
☒ Oath or Declaration of inventor(s) for DO/EO/US.
☐ Copy of Article 19 amendments. ☐ Translation of Article 19 amendments into English.
The Article 19 amendments ☐ have ☐ have not been entered.
☐ The International Preliminary Examination Report in English and its Annexes, if any.
☐ Copy of the Annexes to the International Preliminary Examination Report (IPER).
☐ Translation of Annexes to the IPER into English.
The Annexes ☐ have ☐ have not been entered.
☒ Preliminary amendment(s) filed 20 OCT 99 and _____
☒ Information Disclosure Statement(s) filed 20 OCT 99 and _____
☒ Assignment document.
☐ Power of Attorney and/or Change of Address.
☐ Substitute specification filed _____
☐ Verified Statement Claiming Small Entity Status.
☐ Priority Document.
☐ Copy of the International Search Report ☐ and copies of the references cited therein.
☐ Other:

for 09/403,429
attn. S. Tran



Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

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FORM PCT/DO/EO/903 (December 1997)